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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,300	08/21/2001	Todd Lewis Talarico	35780/233666 (5780-5)	8297

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,300

Applicant(s)

TALARICO ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-19 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-19 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 92004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO APPLICANTS' ARGUMENTS

- 1) Acknowledgment is made of Applicants' after-final response filed 10/26/04 in response to the final Office Action mailed 07/28/04.

Status of Claims

- 2) No claims have been amended via the amendment filed 10/26/04.
Claims 12-19 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Information Disclosure Statement

- 5) Acknowledgment is made of Applicants' information disclosure statement filed 09/20/04. This information disclosure statement (IDS) was filed after the mailing date of the final Office Action on 07/28/04. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the Office has considered the information disclosure statement.

Finality Withdrawn

- 6) The finality of the previous Office Action mailed 07/28/04 is withdrawn in light of the new grounds of art rejections set forth below. The art rejections are based on a prior art reference(s) submitted by Applicants to the Office via the IDS filed *after* the mailing of the final rejection. Applicants are asked to note that the instant Office is hereby made Final, since the new ground of art rejection is necessitated by Applicants' submission of relevant prior art only after the mailing of the final Office Action dated 07/28/04.

Rejection(s) Withdrawn

- 7) The rejection of claims 12-16 and 18 made in paragraph 19 of the Office Action mailed 12/19/03 and maintained in paragraph 6 of the Office Action mailed 07/28/04 under 35 U.S.C. § 102(b) as being unpatentable over Woghiren *et al.* (*Bioconj. Chem.* 4: 314-318, 1993) in view of

Miles *et al.* (*Art. Cells Boold Subs. Immob. Biotech.* 25: 315-326, 1997 - Applicants' IDS) or Iwashita *et al.* (*Biomat. Art. Cells Art. Org.* 16: 271-280, 1988, already of record) or Rausch *et al.* (US 5,084,558 - Applicants' IDS) and Katsunuma *et al.* (US 4,229,571) or JP 53038617 ('617), is withdrawn in light of the new rejection(s) set forth below based on a prior art reference submitted by Applicants to the Office via the IDS filed *after* the mailing of the final rejection.

8) The rejection of claims 17 and 19 made in paragraph 20 of the Office Action mailed 12/19/03 and maintained in paragraph 7 of the Office Action mailed 07/28/04 under 35 U.S.C. § 103(a) as being unpatentable over Woghiren *et al.* (*Bioconj. Chem.* 4: 314-318, 1993) as modified by Miles *et al.* (*Art. Cells Boold Subs. Immob. Biotech.* 25: 315-326, 1997 - Applicants' IDS) or Iwashita *et al.* (*Biomat. Art. Cells Art. Org.* 16: 271-280, 1988, already of record) or Rausch *et al.* (US 5,084,558 - Applicants' IDS) and Katsunuma *et al.* (US 4,229,571) or JP 53038617 ('617) as applied to claims 16 and 18 above, and further in view of Feola *et al.* (US 5,439,882, already of record), is withdrawn in light of the new rejection set forth below based on a prior art reference submitted by Applicants to the Office via the IDS filed *after* the mailing of the final rejection.

Arguments Moot

Applicants' arguments with respect to all art rejections have been considered but are moot in view of the withdrawal of, or the new ground(s) of rejection.

Rejection(s) under 35 U.S.C. § 102

9) Claims 12, 13, 15, 16, 18 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nho *et al.* (US 5,234,903 - Applicants' IDS).

Nho *et al.* taught a method of preparing a chemically modified hemoglobin solution comprising dissolving an activated polyethylene oxide or PEG in toluene/dichloromethane solvent, filtering the activated PEG solution via at least one filter, and combining the resultant solution with a hemoglobin solution. The hemoglobin is pyridoxylated stroma-free hemoglobin, and the method steps are accomplished under sterilizing conditions (i.e., aseptically). The filtration reduced the endotoxin and pyrogen contaminant levels to < 0.1 EU. See sections 2.4 - 2.6; 5.1.2; columns 12-14 and 16; the whole of section 6 including 6.1.5; section 10.2 and Table IV; section 5.1.4; and column 18 lines 51-54.

Claims 12, 13, 15, 16, 18 and 19 are anticipated by Nho *et al.*

Rejection(s) under 35 U.S.C. § 103

10) Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nho *et al.* (US 5,234,903 - Applicants' IDS) as applied to claim 13 above and further in view of Woghiren *et al.* (*Bioconj. Chem.* 4: 314-318, 1993, already of record).

The teachings of Nho *et al.* are explained above, which do not expressly teach methanol as a solvent for dissolving the activated PEG.

However, the use of an alternative solvent such as methanol to dissolve the activated PEG was well known in the art at the time of the invention. For example, Woghiren *et al.* taught the use of methanol as a solvent to dissolve the activated PEG (see 'Experimental Procedures', especially on page 315).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use an alternative solvent such as Woghiren's methanol in place of Nho's toluene to produce the instant invention with a reasonable expectation of success. Substitution of one solvent in a prior art method with another art-known, alternative solvent for the same purpose of dissolution of an activated PEG is well within the realm of routine experimentation, would have been obvious to one of ordinary skill in the art, and would have brought about similar effects or results.

Claim 14 is *prima facie* obvious over the prior art of record.

11) Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nho *et al.* (US 5,234,903 - Applicants' IDS) as applied to claim 16 above.

The teachings of Nho *et al.* are explained above. Although Nho *et al.* are silent about the type of the filter used for the filtration of activated PEG, Nho *et al.* expressly taught the filter used for filter sterilization of the PEG-Hb- containing solution to be a 0.2 micron Zetapor membrane (i.e., nylon) filter (see sections 6.1.5 and 6.2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use Nho's 0.2 micron Zetapor membrane (i.e., nylon) filter to filter the activated PEG solution before combining it with a hemoglobin solution to produce the instant invention with a reasonable expectation of success, since Nho *et al.* have shown that a Zetapor membrane filter does sterilize an activated PEG-containing solution and renders it free of endotoxin

contaminants. One of skill in the art would have been motivated to produce the instant invention for the expected benefit of ensuring sterility of the intermediate PEG solution by rendering it free of endotoxin contaminants since such a sterile intermediate product is ideally desired in the art for the preparation of a final product (aPEG-Hb) meant for *in vivo* administration.

Claim 17 is *prima facie* obvious over the prior art of record.

Relevant Prior Art

12) The prior art made of record and not relied upon currently in any of the rejections is considered pertinent to Applicants' disclosure.

- Meyering *et al.* (US 4,929,354) taught that the ZETAPOR filter membrane is a nylon microporous filter membrane (see lines 13-15 in column 2).

Remarks

13) Claims 12-19 stand rejected.

14) **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.

16) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

November, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER